

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ELETROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH
INCREASED STRENGTH

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ELETROSTATICALLY CHARGED NASAL APPLICATION
PRODUCT WITH INCREASED STRENGTH

(Attorney Docket No. ALW-104A)

INCORPORATIONS BY REFERENCE TO RELATED CASES

The present invention relates to electrostatically charged topical
nasal application products which have been developed and improved
since their original development as set forth in two previously issued
United States patents. For this reason, the entire specification and claims
are incorporated herein in their entirety by reference, as to United States
Patent Number 5,468,488, entitled "ELECTROSTATICALLY
CHARGED NASAL APPLICATION PRODUCT AND METHOD"
issued to Ashok L. Wahi, inventor, on November 21, 1995, and United
States Patent Number 5,674,481, entitled "ELECTROSTATICALLY
CHARGED NASAL APPLICATION PRODUCT" ISSUED TO Ashok
L. Wahi on October 7, 1997.

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BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to products for restricting the flow of airborne contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage. This prevents or reduces the inflow of airborne contaminants to the nasal passage.

2. Information Disclosure Statement

United States Patent Number 5,468,488 describes a method for restricting the flow of airborne contaminants into a nasal passage. It involves creating an electrostatic field in an area near a human nasal passage. The electrostatic field may either repel or attract airborne contaminants or both. The method involves applying a topical application having a plurality of masses of one or more electrostatic materials, and a carrier having the plurality of masses dispersed therein. The masses have an average cross sectional area of about one square

millimeter to about 50,000 square millimeters, and are of sufficient charge to create an electrostatic field which will prevent at least some airborne contaminants from passing into a human nasal passage. The topical application may be in the form of a solution, a semisolid, a solid, a spray solution or a vaporizable solution.

United States Patent Number 5,674,481 describes a product and method for restricting the flow of airborne contaminants into a nasal passage. It involves creating an electrostatic field in an area near a nasal passage. The electrostatic field may either repel or attract airborne contaminants or both. The product may take the form of a plurality of masses of one or more electrostatic materials, the masses have an average cross sectional area of about one square millimeter to about 50,000 square millimeters, the mass being of sufficient charge to create an electrostatic field which will prevent at least some airborne contaminants from passing into a nasal passage. There is also a carrier material with the plurality of masses dispersed therein. The product may

be a topical solution, a semi solid, a solid, a spray solution or a vaporizable solution. Alternatively, it may be in a form which includes a substance for the carrier and, in one preferred embodiment, the substrate would be an adhesive material such as a bandage.

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The aforesaid references describe various methods and products for restricting airborne contaminant flow to the nasal passage area utilizing the suggested formulae described therein. It has now been discovered that utilization of at least 10% of one specific active electrostatically charged polymer provides significantly increased charge density and efficacy as compared to other electrostatic polymers at lower, the same or higher concentrations than the present invention levels of the poly (dimethyl diallyl ammonium chloride). For this reason, notwithstanding the prior art, the present invention is neither taught nor rendered obvious thereby.

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SUMMARY OF THE INVENTION

5 The present invention relates to a nasal topical application product
for restricting the flow of airborne contaminants into a human nasal
passage by creation of an artificial electrostatic field near the human
nose This nasal application product includes: (a) a plurality of masses of
one or more electrostatic polymers; and, (b) a topical carrier having the
plurality of masses dispersed through a portion thereof. In the present
invention, at least one of the electrostatic polymers is a poly (dimethyl
diallyl ammonium chloride) polymer and is included in the product in an
10 amount of at least 10% by weight, based on the total weight of the
plurality of masses of one or more electrostatic polymers and the topical
carrier.

The nasal application product of the present invention may be
selected from the group consisting of topical solutions, semisolids, spray
15 solutions and vaporizable solutions. Topical applications may be in the
form of ointments, pastes, creams and gels.

The carrier of the nasal application product of the present invention may be selected from the group consisting of diluents, volatile spray carriers, lotions, solvents, gels and hydrogels. When the carrier is a diluent, it may be selected from the group consisting of glycols, glycerines, organic surfactants, esters being of unsaturated fatty acids, and mixture thereof. When the carrier is a volatile spray carrier, it may be selected from the group consisting of water, natural oils, glycols, organic surfactants and mixtures thereof. When the carrier is a lotion, it may be selected from the group consisting of polyethylene glycols, natural oils, silicones, homogenizers, and mixtures thereof. When the carrier is a gel, it may be selected from the group consisting of three dimensional polymeric matrices of natural polymers, synthetic polymers, copolymers, and mixtures thereof.

In some preferred embodiments of the nasal application product of the present invention, the carrier includes at least one homogenizer and at least one glycol polymer.

In preferred some embodiments of the present invention nasal application product, the carrier includes about 1 to about 5% by weight of a glycol compound and about 60 to 85% by weight of water, based on the total weight of the plurality of masses of one or more electrostatic polymers and the topical carrier. Preferred nasal application product topical carrier formulae include:

- (a) about 1% to about 5% by weight of a glycol compound selected from the group consisting of polyethylene glycol, polypropylene glycol and mixtures thereof;
 - (b) about 60% to about 85% by weight of water; and,
 - (c) about 0% to about 2.5% of one or more stearate compounds;
- all of the above weight percentages being based on the total weight of the plurality of masses of one or more electrostatic polymers and the topical carrier.

The present invention nasal application products may further include a substrate containing the topical carrier with a plurality of

masses of one or more electrostatic polymers dispersed through at least a portion thereof. The substrate may be a flexible substrate, such as a cloth or other woven material or a synthetic sheet material with an adhesive thereon, e. g., a bandage type of substrate.

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BRIEF DESCRIPTION OF THE DRAWINGS

The present invention should be more fully understood when the specification herein is taken in conjunction with the drawings appended hereto wherein:

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FIG. 1 shows a schematically the product concept of the present invention;

FIG. 2 shows a side partial stylized view of a human illustrating a typical electrostatic field around a human nasal passage;

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FIG. 3 shows the same stylized human outline as in FIG. 2 but with an artificially created electrostatic field near a persons nose to restrict the flow of airborne contaminants into the nasal passages;

FIG. 4 shows another alternative present invention embodiment wherein a combination of artificially created electrostatic fields are shown; and,

FIG. 5 shows a mild artificially created electrostatic field.

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DETAILED DESCRIPTION OF THE PRESENT INVENTION

The Figures 1 through 5 are briefly described above and are identical to the drawings set forth in the two issued patents incorporated by reference stated above. As such, the detailed explanation and description set forth therein is incorporated herein and, thus, not unnecessarily repeated here.

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The present invention is based on the surprising and unexpected discovery that a significant increase in electrostatic charge density is achieved with the present invention by use of at least 10 % by weight of poly (dimethyl diallyl ammonium chloride). This is contrary to experiences of the inventors wherein increase in the active (electrostatic

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polymer) after a level achieved at less than 8 % or so, did not significantly increase the electrostatic charge density. However, in the case of the present invention, a charge density increase of about 20 % to 25 % was realized.

The following examples are representative of the present invention:

EXAMPLE #1

<u>Ingredient</u>	<u>% age composition by weight</u>
1. Deionized Water	75.9
2. Potassium Sorbate	0.1
3. Celquat SC 240 C	3.9
4. Polawax 5% in water	4.9
5. Agequat 400	12.9
6. Arlacel 165	1.0
7. Tween 60	0.1
8. Propylene Glycol	<u>1.2</u>
	<u>100.0</u>

EXAMPLE #2

<u>Ingredient</u>	<u>% age composition</u>
1. Deionized water	73.5
2. Celquat SC 240 C	3.8
3. Agequat 400	12.6
4. Polawax 5% in water	9.5
5. Potassium Sorbate	0.1
6. Necon LO	<u>0.5</u>
	<u>100.0</u>

EXAMPLE #3

1. Deionized water	84.9
2. Celquat SC 240 C	4.0
3. Agequat 400	11.0
4. Potassium Sorbate	<u>0.1</u>
	<u>100.0</u>

Generic/Chemical name of the above ingredients are:

Celquat SC 240 C; Quarternary Cellulosic Derivative

Polawax; Fatty Alcohol, Polysorbate Blend

Agequat 400; Poly(Dimethyl Diallyl Ammonium Chloride)

Arlacel 165; Glycerol Monostearate and Polyethylene Stearate

5 Necon LO; A surfactant

Tween 60; Polysorbate

Propylene Glycol; 1,2-Propane Diol

Brief Process of Formulation:

10 In all of the above Examples, the ingredients are added one by one,
at room temperature, in the order listed to water, while stirring. No new
ingredient is added until the one added before was dispersed completely.

15 Polawax and Arlacel were dispersed by warming the mixture, to 60
degrees C., over a water bath. After all the ingredients were added, the
contents were mixed well for uniformity, let cool to room temperature
and bottled.

EXAMPLE #4

<u>Ingredient</u>	<u>Weight (Kg/15 Kg)</u>	<u>%w/w</u>
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1. Polawax (5% dispersion)	0.7500	5.00
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2. Propylene Glycol	0.3000	2.00
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5 3. Celquat SC-240C	0.6000	4.00
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4. Agequat 400	1.6500	11.00
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5. Methylparaben	0.0300	0.20
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6. Propylparaben	0.0150	0.10
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7. Tetrasodium Edetate	0.0075	0.05
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10 8. Arlacel 165	0.1500	1.00
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9. Tween 60	0.0150	0.10
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10. Germall-II	0.0450	0.30
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11. Water	<u>11.4375</u>	<u>76.25</u>
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TOTAL	15.0000	100.00
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15 Prodedure:

In a suitable container prepare a 5% dispersion of Polawax in water by mixing 37.5 g in 750 g of water previously heated at 70 plus or minus 5 degrees C. (Step A)

In a tared stainless steel container with 10 Kg of water previously heated at 70 plus or minus 5 degree C and stirred mechanically, add Celquat SC-240C gradually, directly into the vortex. Make sure no clumps are formed. As the dispersion thickens, increase the speed of the mixer enough to maintain the movement of the surface and the bulk of the dispersion. Allow mixing for one to one and a half hour to get a clear, uniform, transparent dispersion at 70 degrees C.

Add sequentially Tetrasodium Edetate, Arlacel 165, Tween 60 and Agequat 400 with mixing, making sure that each ingredient is completely dissolved or dispersed before adding the next one. (Step B)

Add dispersion in step A to the dispersion in step B with continued mixing. Allow the mixture to cool down gradually to about 50 degrees C. (Step C)

In a suitable container dissolve Methylparaben, Propylparaben and Germall-II in Propylene Glycol and heat. (Step D)

When the temperature of the mixture from step D reaches 50 degrees C add solution in step C with continued mixing. (Step E)

5 Dilute the combined mixture from step E to 15.0 Kg by adding Water previously heated at 50 degrees C and continue mixing.

Allow the product to cool to 30 degrees C to form a gel.

Transfer the bulk gel to suitable polyethylene lined containers.

Comparative tests of electrostatic charge density revealed an
10 increase of 20 % to 25 % as compared to prior art formulations and as compared to other formulations having over 10 % electrostatic polymer using actives other than poly (dimethyl diallyl ammonium chloride).

Obviously, numerous modifications and variations of the present invention are possible in light of the above suggestions. It is therefore
15 understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.